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09/593,173 06/12/00 GUARNA

A 1195-003

EXAMINER

HM12/0326

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ART UNIT

PAPER NUMBER

1625

DATE MAILED:

03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/593,173

Applicant(s)
Guarna Et. Al.

Examiner
Binta Robinson

Group Art Unit
1625



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-17 is/are pending in the applicat

Of the above, claim(s) 4-9, 16, and 17 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 10-15 is/are rejected.

☒ Claim(s) 3 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 10, 11-15, drawn to octahydro compounds of formula I in claim 1, methods of treating, pharmaceutical compositions classified in class 546, subclass 95.
 - II. Claims 1-3, 10, 11-15, drawn to decahydro compounds of formula I in claim 1, methods of treating, pharmaceutical compositions, classified in class 546, subclass 95.
 - III. Claims 1-3, 10-15, drawn to all other compounds not in groups I and II, methods of treating, pharmaceutical compositions, classified in class 546, subclass 95 and class 514, subclass 294.
 - IV. Claims 4-7, drawn to alternate processes of preparing the compound of formula I in claim 1.
 - V. Claim 8, drawn to a process of preparing the compound of formula I in claim 1, classified in class 546, subclass 95 will be rejoined with Group I when Group I compounds are allowed, but of the same scope.
 - VI. Claim 9, drawn to the compound of formula 6, classified in class 546, subclass 153.
 - VIII. Claims 16, drawn to agricultural compositions, classified in class 514, subclass 306.

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IX. Claims 17, drawn to a process for plant growth regulation wherein an effective quantity of a composition according to claim 16 is distributed on the seeds and/or the plants to treat, classified in class 504, subclass 246.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can be used as agricultural compositions regulating plant growth, pharmaceutical compositions for treating acne, baldness, or prostatic cancer.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Claims 1-17 are generic to a plurality of disclosed patentably distinct species comprising Q, W, R1-R6, X, and n. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. During a telephone conversation with James Costigan on 3/5/01, a provisional election was made with traverse to prosecute the invention of example 11 on page 16 of the specification. The election of species has been used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U. S. C. 121. By virtue of the applicant's election of species, the applicant has elected group I for prosecution also. Applicant is entitled to have one process in either groups IV or V, and IX rejoined for examination along with the elected group when the case is in condition for allowance. According to the procedure in *In re Ochai*, the compounds in the process must be narrowed to the compounds being allowed, See 37 USPQ 2d, page 1127, Fed. Cir. 1995, *In re Brower* 37 USPQ 2d, page 1663, January 1996. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-8, 9, 16, and 17 and other unelected portions of claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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7. Claims 1 and 2 are objected to because of the following informalities: the word "naphtyl" is a misspelling in line 3 and 2 of claims 1 and 2, respectively. Appropriate correction is required.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the broad spectrum of substituents for radicals, R1-R6 in formula I in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 1 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for all radicals R1-R6 equal to all heterocycles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification lacks direction or guidance for placing all of the alleged products in the

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possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

10. Claim 13 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method for the treatment of all pathologies related to 5 alpha-reductase enzymes by administration to the patient of a pharmaceutically active amount of a pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

11. Claim 14 in part is rejected under 35 U.S.C. 112, first paragraph, because there is not enough data in the specification to warrant all of the divergent uses claimed. The applicant is referred to *In re Fouché* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is also referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. of App. And Inter 1986).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 15 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1 and 2 in part, the term "heterocycle" is indefinite. It is unclear as to which heterocycles the claims are referring to. Appropriate clarification is required.

B. Claim 2 in part recites the limitation "(wherein R is as above defined)" in line 8. There is insufficient antecedent basis for this limitation in the claim. The radical R must be defined at claim 2. Claim 2 in part also recites the limitation "(wherein R and R' are as above defined)" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim. The radicals R and R' must be defined at claim 2.

C. Claim 15 in part provides for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 in part is rejected under 35 U.S.C. 101 and 112, second paragraph, because it represents an improper product-use-claim. *Clinical products v. (Brenner, Commissioner of Patents)* 145 USPQ 475 (District Court, DC 1966) and *Ex parte Dunki et. al.* 153 USPQ 678 (Bd of Appeals 1967).

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13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by CA reference 103:195974. (Reference U)

CA Reference 103:194974 teaches the instant compound, 7H-Benzo[c]quinolizine-1,2,3,4-tetracarboxylic acid, tetramethyl ester. At page 667, see the instant compound.

14. The IDS filed 11/24/00 has been considered.

15. Claim 3 in part is objected to because it is based on a rejected claim.


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta Robinson whose telephone number is (703)306-5437.

The examiner can normally be reached on Monday through Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703)308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

BMR

March 23, 2001



ALAN L. ROTMAN
PRIMARY EXAMINER